AMENDMENTS TO THE CLAIMS:

Please amend claims 1, 3, 4, 6, 8, 10, 17, 21, 26 and 35, and cancel claims 2, 5, 12, 24, 39 and 47 without prejudice or disclaimer as follows. This listing of claims replaces all prior versions, and listings of claims, in the application.

LISTING OF CLAIMS:

1. (Currently Amended) A combination, comprising:

a test system for detecting a fetal-restricted antigen or estriol in a sample, wherein the <u>test system comprises an antibody that specifically binds to a fetal restricted antigen or an antibody that specifically binds to estriol, and the</u> detected fetal-restricted antigen or estriol is indicative of a risk of preterm delivery; and

a <u>progestational agent selected from among</u> ~~progesterone related agent or~~ progesterone, 17-α-hydroxyprogesterone, 17-α-hydroxyprogesterone caproate and an omega-3 fatty acid.

2. (Canceled)

3. (Previously Presented) The combination of claim 1, wherein the test system comprises an immunoassay test strip to detect a fetal restricted antigen or estriol in a sample.

4. (Currently Amended) The combination of claim 1, <u>further comprising a sample collection device,</u> wherein the sample is <u>selected from among a</u> body fluid, ~~or~~ a swab of the posterior fornix, <u>a swab of</u> the cervical canal, <u>a swab of</u> the ectocervix and~~/or~~ <u>a swab of</u> the external cervical os.

5. (Canceled)

6. (Currently Amended) The combination of claim 1, wherein the ~~progesterone-related~~ <u>progestational</u> agent is 17-α-hydroxyprogesterone or 17-α-hydroxyprogesterone caproate.

7. (Original) The combination of claim 1, wherein the omega-3 fatty acid is docosahexaenoic acid.

8. (Currently Amended) A combination for screening and treating a subject, comprising:

a) a solid support, comprising an anti-(preterm delivery marker) antibody; and

b) a progestational agent, <u>wherein the progestational agent is selected from among progesterone, 17-α-hydroxyprogesterone, 17-α-hydroxyprogesterone caproate and</u> an omega-3 fatty acid..

9. (Original) The combination of claim 8, wherein the anti-(preterm delivery marker) antibody is selected from the group consisting of an anti-(fetal restricted antigen) antibody, an anti-(fetal restricted antigen class) antibody, and an anti-estriol antibody.

10. (Currently Amended) The combination of claim 8, further comprising a second antibody, wherein the second antibody is an anti-(fetal restricted antigen) antibody directed to the same antigen.

11. (Previously Presented) The combination of claim 8, further comprising one or more anti-(membrane rupture marker) antibodies.

12. (Canceled)

13. (Original) The combination of claim 8, wherein the progestational agent is 17-α-hydroxyprogesterone or 17-α-hydroxyprogesterone caproate.

14. (Original) The combination of claim 8, wherein the progestational agent comprises docosahexaenoic acid.

15. (Previously Presented) The combination of claim 8, comprising three or more antibodies, wherein the antibodies include an anti-fibronectin antibody, an anti-estriol antibody, and an anti-(insulin-like growth factor binding protein one) antibody.

16. (Canceled).

17. (Currently Amended) A method of screening and treating a subject, comprising:

(a) monitoring the level of a marker of preterm or imminent delivery in a body fluid sample from a subject following about 20 weeks of gestation; and

(b) if the level is indicative of a risk for preterm or imminent delivery, administering a progestational agent, whereby delivery is delayed, wherein the progestational agent is selected from among progesterone, 17-α-hydroxyprogesterone, 17-α-hydroxyprogesterone caproate and an the group consisting of a naturally or synthetically produced omega-3 fatty acid, a naturally or synthetically produced hormone normally secreted by the corpus luteum, placenta, or adrenal cortex, and derivatives and mixtures thereof.

18. (Original) The method of claim 17, wherein the level is equal to or above a predetermined level.

19. (Original) The method of claim 17, wherein the level is equal to or below a predetermined level.

20. (Original) The method of claim 17, wherein the marker is unconjugated estriol.

21. (Currently Amended) The method of claim 17, wherein the marker is the ratio of the level of estriol in the body fluid sample to the level of progesterone in the body fluid sample.

22. (Original) The method of claim 17, wherein the marker is a fetal restricted antigen.

23. (Original) The method of claim 22, wherein the fetal restricted antigen is fetal fibronectin.

24. (Canceled)

25. (Original) The method of claim 24, wherein the progestational agent is 17-α-hydroxyprogesterone or 17-α-hydroxyprogesterone caproate.

26. (Currently Amended) A method of screening and treating a subject, comprising:

(a) monitoring the level of a first marker and a second marker of preterm or imminent delivery in a body fluid sample from a subject;

(b) if the level of the first marker is indicative of a risk for preterm or imminent delivery, evaluating the level of the second marker; and

(c) if the level of the second marker is indicative of a risk for preterm or imminent delivery, administering a progestational agent, whereby delivery is delayed, wherein the progestational agent is selected from among progesterone, 17-α-hydroxyprogesterone, 17-α-hydroxyprogesterone caproate and an omega-3 fatty acid.

27. (Original) The method of claim 26, wherein the first marker is a fetal restricted antigen and the second marker is estriol.

28. (Original) The method of claim 27, wherein the fetal restricted antigen is fetal fibronectin.

29. (Previously Presented) The method of claim 27, wherein the estriol is unconjugated estriol.

30. (Original) The method of claim 17, further comprising the steps of:

monitoring the level of a marker for membrane rupture; and

if the level is not indicative of membrane rupture, administering a progestational agent, whereby delivery is delayed.

31. (Original) The method of claim 30, wherein the marker of preterm delivery is selected from the group consisting of estriol and a fetal restricted antigen.

32. (Original) The method of claim 30, wherein the marker of preterm delivery is unconjugated estriol.

33. (Original) The method of claim 30, wherein the marker or preterm delivery is fetal fibronectin.

34. (Original) The method of claim 30, wherein the marker of membrane rupture is insulin-like growth factor binding protein one.

35. (Currently Amended) A method of screening and treating a subject, comprising:

a)   detecting a fetal restricted antigen in a sample from a subject and assessing whether the level of fetal restricted antigen is indicative of a risk of preterm or imminent delivery; and

b)   if the level of fetal restricted antigen is indicative of the risk, ~~detecting estriol in a sample from a subject and assessing whether the level of estriol is indicative of a risk of preterm or imminent delivery;~~

~~c)   if the level of estriol is indicative of the risk, assessing the level of a marker for membrane rupture; and~~

~~d)   if the level of the marker for membrane rupture is not indicative of membrane rupture,~~ administering a therapeutically effective amount of a progestational agent to the subject, whereby delivery is delayed, wherein the progestational agent is selected from among progesterone, 17-α-hydroxyprogesterone, 17-α-hydroxyprogesterone caproate and an omega-3 fatty acid.

36. (Original) The method of claim 35, wherein, wherein the sample contains a body fluid or a swab of the posterior fornix, the cervical canal, the ectocervix and/or the external cervical os.

37. (Original) The method of claim 35, wherein a level indicative of the risk is above a minimum threshold amount.

38. (Original) The method of claim 35, wherein a level indicative of the risk is below a maximum threshold amount.

39. (Canceled)

40. (Previously Presented) The method of claim 35 wherein the sample is obtained after about 12 weeks gestation.

41. (Original) The method of claim 35, wherein the sample is obtained after about 16 weeks gestation.

42. (Original) The method of claim 35 wherein the sample is obtained after about 20 weeks gestation.

43. (Original) The method of claim 35, wherein the administration of the progestational agent is stopped at about 36 weeks of gestation or at the onset of spontaneous labor.

44. (Original) The method of claim 35, wherein the fetal restricted antigen is fetal fibronectin.

45. (Original) The method of claim 35, wherein the progestational agent comprises at least one omega-3 fatty acid or a derivative thereof.

46. (Original) The method of claim 45, wherein the progestational agent comprises docosahexaenoic acid.

47. (Canceled)

48. (Original) The method of claim 47, wherein the progesterone-related agent is 17-α-hydroxyprogesterone or 17-α-hydroxyprogesterone caproate.

49. (Original) The method of claim 35, wherein the therapeutically effective amount of the progestational agent comprises at least about 100 mg/week of the progestational agent.

50. (Original) The method of claim 35, wherein the progestational agent is administered orally, by intramuscular injection, transdermally, or intranasally.

51. (Original) The method of claim 35, further comprising the step of:

if the level of fetal restricted antigen is not indicative of a risk of preterm or imminent delivery, repeating at intervals at least one day apart the steps of detecting the fetal restricted antigen in the sample and assessing whether the level of fetal restricted antigen is indicative of the risk; wherein

if the level of fetal restricted antigen is indicative of the risk, administering a progestational agent to the subject, whereby delivery is delayed.

52. (Original) The method of claim 44, wherein the level indicative of the risk is a minimum threshold value of about 50 ng/mL.

53. (Original) The method of claim 44, wherein the sample is obtained from the posterior fornix.

54. (Original) The method of claim 44, wherein the sample is obtained from the cervical os.

55. (Original) The method of claim 44, wherein the level of fetal fibronectin is determined by the steps of:

a) contacting the sample with an anti-(fetal fibronectin) antibody for a time sufficient to permit antigen-antibody binding to occur;

b) contacting the sample with an insoluble support, to which anti-fibronectin antibody is adhered, for a time sufficient to permit antigen-antibody binding to occur; and

c) detecting anti-(fetal fibronectin) antibody on the insoluble support.

56. (Original) The method of claim 55, wherein material from the sample is contacted with the insoluble support in a region of the insoluble support that contains mobilizable anti-(fetal fibronectin) antibody.

57. (Previously Presented) The method of claim 55, wherein the anti-(fetal fibronectin) antibody is conjugated to a physically detectable label.

58. (Original) The method of claim 55, wherein the step of detecting anti-(fetal fibronectin) antibody comprises the steps of:

a) contacting the insoluble support with a labelled antibody which binds selectively with the anti-(fetal fibronectin) antibody; and

b) detecting the label on the insoluble support.

59. (Original) The method of claim 44, wherein the subject is a preterm subject.

60. (Original) The method of claim 59, wherein the subject is at risk for preterm delivery.

61. (Original) The method of claim 44, wherein the level of fetal fibronectin is determined by the steps of:

a) contacting the sample with an anti-fibronectin antibody for a time sufficient to permit antigen-antibody binding to occur; and

b) detecting formation of an antibody-antigen complex.

62. (Original) The method of claim 61, wherein the step of detecting formation of an antibody-antigen complex further comprises the steps of:

      c)   contacting the sample with an insoluble support comprising an immobilized an anti-(fetal fibronectin) antibody under conditions, whereby fetal fibronectin in the sample binds to the antibody; and

      d)   detecting the anti-fibronectin antibody on the insoluble support.

63. (Original) The method of claim 61, wherein the anti-fibronectin antibody comprises a detectable label.

64. (Original) The method of claim 62, wherein the step of detecting the anti-fibronectin antibody comprises the steps of:

      e)   contacting the insoluble support with a labeled antibody that binds selectively with the anti-fibronectin antibody; and

      f)   detecting the label on the insoluble support.